



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,518	10/18/2001	Frederick W. Trombley III	VI/00-013	7226
21140	7590	08/11/2004	EXAMINER	
GREGORY L BRADLEY MEDRAD INC ONE MEDRAD DRIVE INDIANOLA, PA 15051			SIRMONS, KEVIN C	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

7W

Office Action Summary	Application No. 09/982,518	Applicant(s) TROMBLEY ET AL.	
	Examiner Kevin C. Sirmons	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 2, 8-10, 30, 40-44 and 46 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25-29 is/are allowed.
- 6) ☒ Claim(s) 1, 3-6, 11-24, 31-39 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/6/02</u> | 6) <input type="checkbox"/> Other: _____ |

L

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I and Species II in the reply filed on 7/16/04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim 7 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Species I, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/16/04.

Applicant has withdrawn claims 2, 8-10, 30, 40-44 and 46.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-7, 11-24 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 1, it is unclear what applicant regards as the pressurizing chamber. What is the reference numeral?

As to claim 2, it is unclear what applicant regards as the manual control comprises a chamber. What is the reference numeral?

Art Unit: 3763

As to claim 5, it is unclear what applicant regards as the second actuator. What is the reference numeral?

As to claims 4 and 5, it is unclear how the manual control can comprise a second and third actuator.

As to claim 11, it is unclear what applicant regards as a low-pressure fluid deliver system. What is its reference numeral?

Claim 11 recites the limitation "the syringe pump." There is insufficient antecedent basis for this limitation in the claim.

As to claim 11, it is unclear what applicant regards as the first-third ports. What are the reference numerals for each?

As to claim 32, it is unclear what applicant regards as the stopcock adapted to selectively isolate the pump device, the source of injection fluid, and the per-patient use section. What is the reference numeral?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-6 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Palestrant U.S. Pat. NO. 5,002,528.

Art Unit: 3763

Palestrant discloses an injector system comprising: an injector (22 and/ line entering port 18); a pressurizing chamber in operative connection with the injector (interior of 22 and/or 20); a fluid path in fluid connection with the pressure (the entire fluid pathway of the system of fig. 2); a manual control in fluid connection with the fluid path (25), the manual control comprising at least one actuator (the piston of the plunger (not shown) and the piston of the plunger is fully capable of stopping the injection procedure if no force is applied to the actuator; Note: Claim 1, is so broad that Palestrant has at least several different interpretations because an injector has no structure, the pressurizing chamber has no structure, the fluid path has no structure and a manual control has very little structure; as to claim 3, the device of Palestrant is fully capable of performing applicants function; as to claim 5, (60); as to claim 6, (stopcock 20); As to claim 11, (see above rejections and fig. 2)

Claims 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Woelpper et al U.S. Pat. No. 55,69,208.

Woelpper discloses a pressurizing device (20, 18, and 58); a low pressure fluid delivery system (figs. 2-8); a pressure isolation mechanism (64) having a first-third port (figs. 2-8); note: the valve of Woelpper is fully capable of performing the function as set forth in claim 11; as to claim 12, (68, 72).

Claims 11, 14-18 and 24 are rejected under 35 U.S.C. 102^e(**●**) as being anticipated by Duchon et al U.S. Pat. No. 6,221,045

Duchon discloses a pressurizing device (figs. 1 and 2A) as to claim 24, (38); as to claim 14, as source (22); a drip chamber (18); a detector (160); as to claims 15-17, (figs. 1-2 and 3b); as to claim 18, (14).

Art Unit: 3763

Claims 11, 13, 31-33, 35-38 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Genese U.S. Pat. No. 4,243,031.

Genese discloses a fluid path set comprising: a multi-patient use section (fig. 1); a per-patient use section (10 to 25); as to claim 32, (16), as to claim 33, (fig. 1); as to claims 35-36, (figs. 2-5); as to claim 37, (fig. 1); as to claim 38, (fig. 1); as to claim, 39, (fig. 1); as to claim 45, (21); as to claims 11 and 13, figs. 1, 4 and 5.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 31-39 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 5, 11-15 and 18-22 of copending Application No. 10/237,139. Although the conflicting claims are not identical, they are not patentably distinct from each other because are directed to pressure isolation mechanism and fluid delivery system.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Art Unit: 3763

Allowable Subject Matter

Claim 19-23, would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

29
Claims 25-29 are allowable over the prior art of record.

Conclusion

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703) 306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.



Kevin C. Sirmons
Patent Examiner
8/9/04